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EXAMINER	
SCHMIDTMANN, BAHAR	

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1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,787	SOMMEMEYER, KLAUS	
	Examiner	Art Unit	
	BAHAR SCHMIDTMANN	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/08/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/EP2005/001252, filed 08 February 2005, which claims foreign priority under 35 U.S.C. §119(a-d) to DE 102004006249.8, filed 09 February 2004. Currently an English language translation of this foreign priority document has not been made of record.

Claims 1-23 are pending in the current application. Claim 23 is withdrawn as being drawn to a nonelected invention, see below. Claims 1-22 are examined on the merits herein.

Election/Restrictions

Applicant's election of Group I, claims 1-22 in the reply filed on 13 November 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).

Claim 23 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 13 November 2009.

Nucleotide Sequence

The electronic copy and the paper copy of the Nucleotide Sequences submitted 29 October 2008 and 08 August 2006, respectively, is acknowledged.

Information Disclosure Statement

The Information Disclosure Statement submitted 08 August 2006 is acknowledged and considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 16-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing a conjugate from a polynucleotide and a polysaccharide having a reducing sugar, does not reasonably provide enablement for producing a conjugate from a polynucleotide and any and all types of polysaccharides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a

disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1)/(5) *The Nature of the Invention/The Breadth of the Claims:*

The instant invention is drawn to a method for producing a conjugate from any polynucleotide having a functional amino group and any polysaccharide. The instantly claimed invention comprises the steps of "provision of an aldonic acid" of the polysaccharide or polysaccharide derivative.

(2)/(4) *The State of the Prior Art/The Predictability or Unpredictability of the Art:*

Formation of an aldonic acid from a reducing sugar is well known in the art and can be accomplished from a variety of experimental techniques. However, formation of an aldonic acid from any polysaccharide is not known. Polysaccharides and oligosaccharides are composed of monosaccharides glycosylated together. Some oligossacharides and monosaccharides can be chemically modified to an aldonic acid, as in the case of reducing sugars such as maltose, a structural component of starch (Hecht, *Bioorganic Chemistry: Carbohydrates*, p.41-42, cited in PTO-892). However, some oligosaccharides and monosaccharides cannot be modified to an aldonic acid as in the case of non-reducing sugars such as sucrose.

Also, carbohydrates have multiple sites of functionality, i.e. multiple hydroxyl groups and/or amine groups that can possibly react with an oligonucleotide. Provision of an aldonic acid ensures reaction at the carboxylic acid moiety of the polysaccharide. However, this provision, which is necessary to ensure the conjugate forms, requires that the polysaccharide have at least one reducing sugar. As a result, forming a conjugate cannot necessarily be formed between a polynucleotide and any polysaccharide. Therefore, forming a conjugate between a polynucleotide having a functional amino group and any polysaccharide is highly unpredictable.

(3) *The Relative Level of Skill in the Art:*

The relative level of skill in the art is high.

(6)/(7)*The Amount of Direction or Guidance Present*/The presence or absence of working examples:

The specification describes formation of conjugates from hydroxyethyl starch (HES) and Spiegelmer of Seq ID No. 1 (p.16-18 and 20-25, examples 1 and 4-14).

(8)*The Quantity of Experimentation Needed:*

Based on the unpredictable nature of the invention and the state of the prior art and the breadth of the claims, one of ordinary skill in the pertinent art would be burdened with undue experimentation study to determine whether any polysaccharide would successfully conjugate to the polynucleotide.

> Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which polysaccharides, if any, would produce the polynucleotide-polysaccharide conjugate with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "polysaccharide or a derivative thereof", "alcohol derivative", and "carbonate derivative" in claims 1 and 7 renders the claim and its dependent claims 2-22 herein indefinite. The recitation of a "derivative" is not clearly defined in the specification, and therefore does not set forth the metes and bounds of the terms "derivative"

The Merriam-Webster's Online Dictionary defines "derivative" as "a chemical substance related structurally to another substance and theoretically derivable from it" (PTO-892, Ref. U).

Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "polysaccharide or a derivative thereof", "alcohol derivative", and "carbonate derivative" herein. One of ordinary skill in the art would clearly recognize that a "polysaccharide derivative", "alcohol derivative" and/or "carbonate derivative" would read on those compounds having any widely varying groups that could be used to substitute the compound. Any significant structural variation to a compound would be reasonably expected to alter its properties; e.g. physical, chemical, physiological effects and functions.

Thus, it is unclear and indefinite as to how the "derivative" herein is encompassed thereby.

The recitation "functional amino group" in claims 1, 17, 19, 20 and 21 render the claims and its dependent claims herein indefinite. Similarly the recitation "functional nucleic acid in claim 17 renders the claim and its dependent claims herein indefinite. Neither "functional amino group" nor "functional nucleic acid" are defined in the specification and therefore does not set forth the metes and bounds of the term "functional".

TheFreeDictionary.com defines "functional" as capable of performing, operative; as well as involving function rather than a physiological or structural cause (cited in PTO-892)

The term "functional" does not allow one of ordinary skill to readily envisage the myriad of structures that could be encompassed by the term. Hence, one of ordinary

skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "functional amino group" or "functional nucleic acid". Any significant structural variation to a compound would be reasonably expected to alter its properties; e.g. physical, chemical, physiological effects and functions.

Thus, it is unclear and indefinite as to how the "functional" herein is encompassed thereby.

The recitation "number average of the mean molecular weight" in claim 12 and "ratio of weight-averaged molecular weight to number average of the mean molecular weight" in claim 13 renders the claims herein indefinite. The specification does not define the term "number average of the mean molecular weight". It is not know if Applicant was simply referring to the "average molecular weight", also known as the "mean molecular weight", or if Applicant was referring to polydispersity?

Because of the high level of uncertainty as to what the claim refers to and what is required of the invention as claimed, claims 12-13 are not further examined on the merits herein.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat.

App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "aldonic acid ester", and the claim also recites "activated aldonic acid ester" which is the narrower statement of the range/limitation. Claims 5, 7, 11, 14, 15, 18 and 19 additionally recite a broad recitation followed by a narrow limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook (WO94/01448, cited by Applicant in Information Disclosure Statement) in view of Sommermeyer et al. (US Pre-Grant Publication 2005/0063943, cited in PTO-892; English equivalent of WO02/080979, cited by Applicant in Information Disclosure Statement) and in further view of Vallazza et al. (*Acta Crystallographica Section D*, cited in PTO-892).

Cook teaches an oligonucleotide-dextran conjugate (abstract). Cook teaches that conjugating oligonucleotides to specific classes of groups such as sugars improve their uptake into cells and/or improves their stability (p.1, third paragraph). Cook teaches the conjugates can be used as specific antiviral agents, antibacterial, anti-parasitic, anticancer and/or therapeutic agents for autoimmune diseases (p.18-19)

Cook teaches the moiety, i.e. dextran may be attached to the 5'end of the oligonucleotide via an $-NH_2-(CH_2)_6-$ linker (i.e. 5-aminohexyl), (p.5, second paragraph). Cook teaches the oligonucleotide ester can be produced via the active ester of the pharmaceutically active substrate with the 5'-amino group of the oligonucleotide (p.7, third paragraph). Specifically, Cook teaches reacting a pharmaceutically active substrate with N-hydroxysuccinimide (abbreviated NHS) to form the pharmaceutically active substrate ester, which is then further treated with dicyclohexyl carbodiimide couping agent (abbreviated DCC), which is then reacted with the aminohexyl linker that is attached to the 5'-phosphate moiety of the oligonucleotide (p.8, second paragraph). Cook teaches modifying the acid of a sugar to form an active ester which can then be coupled with the amino group of an oligonucleotide to form the amide conjugate bond (p.10, first paragraph). Cook teaches that in addition to sugars such as glucose, polysaccharides such as cyclodextrin, dextrans and starch can also be conjugated to the oligonucleotide (p.12, penultimate paragraph).

Cook teaches forming the active ester of dextran using sodium hydroxide as a base in the presence of dimethylformamide (abbreviated DMF), (p.13, embodiment number 3). Cook teaches forming the conjugate in the presence of a sodium phosphate

buffer to ensure a pH of 8.25 (p.14, first paragraph). Cook teaches modifying a pharmaceutically active agent (such as dextran in example 8) to an active ester via NHS, and then reacting the active ester with the 5'-amino oligonucleotide to give the amide conjugate in the presence of a buffer pH 8.25 (p.25, example 1 and p.8, example 8).

Cook et al. teaches that starch has similar or identical carbohydrate monomer units as dextran, therefore the same methods for the conjugation to oligonucleotides can be employed (p.15, last paragraph). Cook et al. teaches the oligonucleotides used may bind to DNA and protect DNA binding sites from the action of enzymes such as DNA methylases (p.16, penultimate paragraph). Cook et al. teaches the oligonucleotides may be utilized to selectively bind to target proteins, or selected regions of target proteins so as to block or restore that protein's function

Cook does not expressly disclose a dry solvent (instant claim 1). Cook does not expressly disclose the aldonic ester being purified prior to conjugation with the polynucleotide (instant claim 3). Cook does not expressly disclose the molar ratio of aldonic acid to alcohol (instant claim 7). Cook does not expressly disclose hydroxyethyl starch as the polysaccharide (instant claims 10-15). Cook does not expressly disclose the nucleic acid as an aptamer or a Spiegelmer (instant claim 17). Cook does not expressly disclose the molecular weight of the polynucleotide (instant claim 18).

Sommermeyer et al. teaches hydroxyalkyl starch/active-substance conjugates for drug delivery (abstract). Sommermeyer et al. teaches the reducing end of the substituted or unsubstituted starch polysaccharide is oxidized to the carboxylic acid, and

then converted to an active ester (paragraphs 0025-0026). Sommermeyer et al. teaches the preferred substituted starch is hydroxyethyl starch, having a C_2:C_6 substitution in the range from 2 to 20, a molar degree of substitution degree of 0.1 to 0.8, and an average molecular weight of 1-300 kDa, preferably 5 to 200 kDa (column 4, paragraphs 0050-0051 and column 9, paragraph 0134).

Sommermeyer et al. teaches forming the conjugate in the presence of dry aprotic polar solvents such as dimethyl sulphoxide (column 14, paragraph 0188). Sommermeyer et al. teaches the oxidized hydroxyalkyl starch can be treated with an activator such as EDC in a molar ratio of 20:1 to 1:20, where a ratio of 6:1 to 1:6 is preferred (column 9, paragraph 0127). Sommermeyer et al. teaches the amide (type of ester) was dialyzed and lyophilized prior to conjugating it with DNA (column 14, paragraphs 0188-0190).

Sommermeyer et al. teaches the active substance can be a nucleic acid, in particular D-DNA, L-DNA, D-RNA, L-RNA, D-nucleic acid or L-nucleic acids (column 3, paragraph 0045). Sommermeyer et al. teaches the average molecular weight of a pharmaceutically active substance conjugated to an oligonucleotide as 32 kDa (column 2, paragraph 0017). Sommermeyer et al. teaches the DNA conjugated to hydroxyethyl starch has a molecular weight of 15678 Da and 15094 Da (column 15, paragraph 0199).

Vallazza et al. teaches aptamers as D-RNA molecules that have high affinity for a wide variety of target molecules (p.1, *Introduction*). Vallazza et al. teaches Spiegelmers as L-RNA mirror images of these molecules which are more resistant to enzymatic degradation, i.e. more stable *in vivo* (p.1, *Introduction*). Vallazza et al.

teaches Spiegelmers are pharmacologically viable because they are biophysically similar to aptamers (p.2, third paragraph). Vallazza et al. teaches that Spiegelmers are promising pharmacological targets because their chiral nature ensures they are stable since their corresponding RNases are not found in nature (p.2, third paragraph).

It would have been obvious at the time the invention was made to use a dry solvent, purify the aldonic ester before conjugation to the oligonucleotide or after, conjugate hydroxyethyl starch to the oligonucleotide, and use aptamers or Spiegelmers as the oligonucleotide.

MPEP 2141 states, "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusatory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at ,82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) " Obvious to try " choosing from a finite

number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

Based on the teachings of the MPEP and KSR above, by employing the rationale in (B) simple substitution of one known element for another to obtain predictable results; (E) " obvious to try " choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success and (G) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention; one having ordinary skill in the art would have been motivated to use a dry solvent, purify the aldonic ester before conjugation to the oligonucleotide or after, conjugate hydroxyethyl starch to the oligonucleotide, and use aptamers or Spiegelmers as the oligonucleotide.

Generally, utilization of an aprotic solvent implies that a proton source such as water is not desired in the reaction conditions. Cook demonstrates that conjugation of the oligonucleotide:polysaccharide is performed in an aprotic solvent, such as DMF. Sommermeyer et al. teaches similarly using an aprotic solvent in producing an oligonucleotide:polysaccharide conjugate and states that the solvent should be water

free, i.e. dry. As stated above, use of a dry solvent minimizes unwanted side reactions that may occur as a result of the proton source. One having ordinary skill in the art would also have been motivated to include a purification step before/after or before and after formation of the active ester and conjugate. Purification of the active ester prior to conjugation can eliminate unwanted side reactions. However, to save time and potential loss of product, one having ordinary skill in the art would also be motivated to withhold an intermediary purification step, and purify after the conjugate has been formed. The latter has been demonstrated by Cook, while the former has been demonstrated by Sommermeyer et al.

Cook suggests that due to dextran's structural similarity to HES, one having ordinary skill in the art would also have been motivated to substitute dextran for HES and form a HES:oligonucleotide conjugate using the procedure taught by Cook. Because Sommermeyer et al. also teaches forming a HES:oligonucleotide complex, one having ordinary skill in the art would have been further motivated to use the hydroxyethyl starch with the same properties taught by Sommermeyer et al. in the procedure taught by Cook.

Both Cook and Sommermeyer et al. teach the polysaccharide:oligonucleotide complex. Furthermore, Sommermeyer et al. teaches the oligonucleotide complex can include D-RNA (i.e. an aptamer) or an L-RNA (i.e. a Spiegelmer). Vallazza et al. teaches that both aptamers and Spiegelmers are pharmaceutically viable and are advantageous in that they have a high affinity for a wide variety of target molecules. One having ordinary skill in the art would therefore be motivated to use aptamers,

especially Spiegelmers since they have the added feature of being more stable to enzymatic degradation.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teaching of the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. BAHAR SCHMIDTMANN whose telephone number is 571-270-1326. The examiner can normally be reached on Mon-Thurs 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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